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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/282,471	03/31/1999	INDU PARIKH	401865/SKYEPHARMA	8677

35437 7590 08/16/2005

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EXAMINER

SPEAR, JAMES M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/282,471

Applicant(s)

PARIKH, INDU

Examiner

James M. Spear

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-36, 38-48, 50, 52 and 55-67 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55-67 is/are allowed.
- 6) ☒ Claim(s) 33, 34, 40-42, 45-48 and 50 is/are rejected.
- 7) ☒ Claim(s) 35, 36, 38, 39 and 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

JAMES M. SPEAR  
PRIMARY EXAMINER

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**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

The Request for Continued Examination and Amendment filed 24 January 2005 has been entered.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 33, 34, 40-42, 45-48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes US 5,091,187 in view of Duclos et al US 5,776,495. Haynes teaches a process for preparing water-insoluble microparticles comprising size reduction by sonication utilizing phospholipids to surface treat active agents. These conventional sonication methods are well known in the art. Column 11, line 14 through column 12, line 61. The reference further teaches mixing active agents using multiple surface active agents considered equivalent to applicants' elements a and b of claim 33.

See example 5, column 16, line 60 through column 17. The reference does not teach fenofibrate, however it does recognize the significance of applying this technology to water-insoluble drugs. Column 12, lines 32-61. Duclos et al is relied on for teaching it is known to process fenofibrate co-precipitates utilizing surfactants such as polyvinylpyrrolidone and polysorbate 80. See Abstract, column 2, line 5 through column 3, line 36, column 5, line 6.

It would have been obvious to one of ordinary skill in the art to use the fenofibrate of Duclos et al in the Haynes sonication process to produce a fenofibrate surface modified microparticulate composition with enhanced serum absorption properties. The motivation being each inventor's desire to provide microparticulate compositions capable of achieving optimum therapeutic efficacy.

4. Claims 35, 36, 38, 39 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 55-67 are allowed.

Claims 1-32, 37, 49, 51, 53 and 54 have been canceled.

Claims 43 and 44 are withdrawn from consideration.

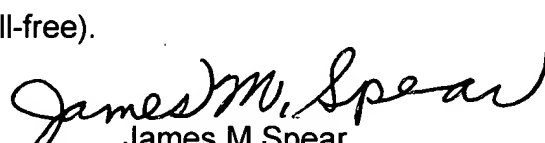
Claims 33, 34, 40-42, 45-48 and 50 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272

0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
James M Spear  
Primary Examiner  
Art Unit 1618

August 12, 2005